REMARKS

The claims are 1-3, 5, 8, 9 and 11-14. Claims 1 and 12 have been amended to more closely define applicants' invention. Claim 14 has been added to capture the subject matter of previously cancelled Claim 4. Claims 1 and 12 are in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-3, 5, 8, 9 and 11-13 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,667,050 ("*Boissonneault et al.*") in view of U.S. Patent No. 3,619,292 ("*Brouillard et al.*") or *Boissonneault et al.* and U.S. Patent No. 4,684,534 ("*Valentine*") in view of *Brouillard et al*. Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 is directed to a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a therapeutically effective amount of a pharmaceutically active ingredient contained in a matrix consisting essentially of from about 15 to about 90% by weight of directly compressible dextrose monohydrate and about 0.5 to about 5 % by weight of sucralose, the % weight being based on the total weight of the tablet, wherein the tablet is formed by direct compression and the tablet is fat-free and the matrix is substantially free of non-saccharide, water soluble polymeric binders.

Boissonneault et al. discloses a chewable oral contraceptive tablet comprising an oral contraceptive agent, a chewable carrier suitable for human consumption, and not comprising a ferrocene compound.

Boissonneault et al. fails to teach the inclusion of dextrose monohydrate and furthermore, does not disclose or suggest forming a tablet by direct compression. As such, Claim 1 is patentable over *Boissonneault et al.*

Brouillard et al. is cited for teaching "a free-flowing tablet containing a binder or a binder-filler, which is a sugar granule. The sugar granule comprises aggregates of cohered microcrystals of dextrose (abstract and col. 1, L 1-20). According to '292 dextrose hydrate provides more advantages when employed in direct compression than in wet granulation or dry granulation…" *See* Office Action dated, January 7, 2009, p. 2, line 21 to p. 3, line 3. However, *Brouillard et al.* does not disclose or suggest the inclusion of sucralose in its tablet composition. As such, Claim 1 is patentable over *Brouillard et al.*

Valentine discloses a chewable tablet composition that is formed using direct compression methods. The tablet composition may include carbohydrate based agglomerated materials such as, dextrose and/or dextrose monohydrate. As with *Brouillard et al., Valentine* does not disclose or suggest the inclusion of sucralose in its tablet composition. As such, Claim 1 is patentable over *Valentine.*

As noted in the Declaration under 37 C.F.R. §1.132 of Frank Bunick, it is not obvious to combine the teachings of *Boissonneault et al., Brouillard et al.* and/or *Valentine.* That is, it is not obvious to one skilled in the art to take a chewable tablet of *Boissonneault et al.* formulated with a high intensity sweetener and dextrose, and substitute the dextrose with dextrose monohydrate as suggested in the present Office Action. The combination of dextrose monohydrate with a high intensity sweetener is known to cause stability issues. Specifically, tablets formed with dextrose monohydrate and a high intensity sweetener have been known to exhibit discoloration and browning as the tablets age. For example, Dr. Bunick points out in his

declaration that aspartame, a high intensity sweetener that is an amine based compound, will react with dextrose over time, resulting in discoloration and browning of tablets formulated as such.

By exposing the tablets to elevated temperature conditions, the tablets are stressed and the bound water in the dextrose monohydrate is released. This facilitates the reaction within the tablets between the dextrose, active ingredients, and/or excipients (i.e., inactive ingredients), which produces undesirable stability issues. Thus, one skilled in the art would not favor the combination of dextrose monohydrate and a high intensity sweetener. As such, Applicants respectfully submit that there is no motivation to combine *Boissonneault et al.* with either *Brouillard et al.* or *Valentine*.

However, the present inventors have surprisingly discovered that when sucralose is used as the high intensity sweetener, that it does not react with dextrose in the presence of increased levels of water. Thus, tablets formulated with sucralose and dextrose monohydrate do not exhibit discoloration or browning.

Therefore, Applicants respectfully submit that Claim 1 is patentable over *Boissonneault et al., Brouillard et al.* and/or *Valentine*, since there is no motivation to combine the references in the proposed manner.

Claim 12 is similar to Claim 1 and also includes the unique combination of dextrose monohydrate and sucralose. For at least the reasons stated above for Claim 1, Claim 12 is patentable over *Boissonneault et al., Brouillard et al.* and/or *Valentine*, since there is no motivation to combine the references as proposed.

Claims 2, 3, 5, 8, 9, 11 and 14 depend from Claim 1, and Claim 13 depends from Claim 12. These claims are also believed to be patentable over the cited references, since they depend from a patentable base claim.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

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